

**PROBITROL- probiotic capsule**  
**PureTek Corporation**

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**Probitrol™**

**STATEMENT OF IDENTITY**

**Probitrol™**

<b>Supplement Facts</b>		
<b>Serving Size:</b>	<b>1 Capsule</b>	
<b>Servings per container:</b>	<b>30</b>	
<b>Amount Per Serving:</b>	<b>%DV</b>	
Proprietary Blend	31 billion CFU	*
Probiotic Bacteria: 2 Strain AcidoBifido Capsule		
Lactobacillus acidophilus		
Bifidobacterium animalis lactis		
* Daily Value (DV) not established		

**Other Ingredients:** Potato Starch, Magnesium Stearate, Ascorbic Acid, Vegetable Capsule (Hydroxypropylmethylcellulose).

**Probitrol™** is an orally administered prescription probiotic formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

**Probitrol™** should be administered under the supervision of a licensed medical practitioner.

**Probitrol™** is manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug Administration (FDA) as food additives or are Generally Recognized as Safe (GRAS) for their intended use.

**DOSAGE**

Usual Adult dose is one capsule once daily, or as prescribed by a licensed medical practitioner.

If you are pregnant or nursing, ask a healthcare professional.

**Probitrol™** should be administered under the supervision of a licensed medical practitioner.

**SAFE HANDLING**

**This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.**

**Probitrol™** should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

**KEEP OUT OF REACH OF CHILDREN**

## **STORAGE**

Store at 20° to 25°C (68° to 77°F).  
Keep in a cool dry place.

## **HOW SUPPLIED HEALTH CLAIM**

**Probitrol™, Probiotic**

Dietary Supplement

NHRIC: 59088-175-54 \*

Bottles contain 30 Capsules

**Manufactured in Canada and  
Distributed in the USA by:**

**PureTek Corporation**

Panorama City, CA 91402

Questions? Call toll-free:

**1-877-921-7873**

\*Does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

† The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

**Probitrol™**

59088-175-54



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List No: 17554 JPA Rev: 38219-01



## PROBITROL

probiotic capsule

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:59088-175
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LACTOBACILLUS ACIDOPHILUS</b> (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)	LACTOBACILLUS ACIDOPHILUS	16000000000 [CFU]
<b>BIFIDOBACTERIUM ANIMALIS LACTIS</b> (UNII: 5307V7XW8I) (BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I)	BIFIDOBACTERIUM ANIMALIS LACTIS	15000000000 [CFU]

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:59088-175-54	30 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		12/29/2020	

## Supplement Facts

Serving Size : **Serving per Container :**

**Amount Per Serving** **% Daily Value**

color  
 shape

size (solid drugs)	25 mm
scoring	1

**Labeler** - PureTek Corporation (785961046)

Revised: 2/2021

PureTek Corporation